

**REMARKS**

Applicants respectfully traverse the rejections under 35 U.S.C. § 112 ¶ 1 because the reasons given for such rejections do not refer to the subject matter that Applicants have elected to claim. The pending claims recite methods “for predicting resistance of a pathogen to at least one therapeutic agent” (and variations thereof), and neural networks “capable of predicting resistance of a disease to a therapeutic agent”.

The rejections allege deficiencies regarding organisms, sequences and therapeutic agents, when there is no pending claim to compositions of matter in the form of claims to organisms, sequences or therapeutic compositions. Accordingly, the reasons for the asserted rejections do not focus on the claimed subject matter.

The Office Action makes allegations concerning diversity of pathogenic agents and genetic sequences, and allegations that some pathogenic agents are not known, that some genetic sequences are not known, and that some relationships between pathogenic agents and diseases are not known. Even if, *arguendo*, these allegations were correct as alleged, they are not relevant in light of the subject matter that the Applicants have elected to claim in the pending claims.

Amount of available information concerning subject matter that is not claimed *per se*, such as pathogenic agents and genetic sequences, bears no relationship with the requirements set forth in 35 U.S.C. § 112 ¶ 1. The pending claims recite elements that a person of ordinary skill in the art is to implement to practice the claimed subject matter, and the specification and drawings provide teachings, direction and support for the claimed subject matter, including support and teachings for the implementation of the claimed subject matter. The requirements set forth in 35 U.S.C. § 112 ¶ 1 are therefore satisfied.

The pending claims rely on a series of elements that are so recited and that are fully and extensively supported in the specification by providing examples of a wide range of pathogens, therapeutic agents, mutations and mutation databases, to which the claimed subject matter can be applied. Teachings on how to practice the claimed subject matter are

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provided in general sections in the specification concerning genotyping methodologies, phenotyping methodologies, and neural networks, and also on actual applications of the claimed subject matter. Furthermore, the specification sets forth that the claimed subject matter is of general applicability, so no limitations as to, for example, specific types of organisms, sequences, and therapeutic agents are to be incorporated into the claimed subject matter.

In contrast, the rejections appear to be based on the imposition of limitations to the claimed subject matter on the basis of elements that are not claimed. Furthermore, the rejections appear to be based also on an alleged lack of specificity on elements that are actually not limiting elements in light of the claimed subject matter and the specification. These bases are not part of an analysis under 35 U.S.C. § 112 ¶ 1, and thus they may not support the present set of rejections.

For at least the reasons set forth herein, Applicants submit that the pending claims comply with 35 U.S.C. § 112 ¶ 1. Applicants respectfully request that the rejections under 35 U.S.C. § 112 ¶ 1 be withdrawn.

Applicants respectfully traverse the rejections under 35 U.S.C. § 112 ¶ 2 because the procedural support cited in the Office Action as a reasoning for an alleged failure to comply with the requirements under 35 U.S.C. § 112 ¶ 2 does not apply to the pending claims. The Office Action cites in this respect M.P.E.P. § 2172.01.

The procedural authority cited in the Office Action concerns “unclaimed essential matter”. As shown below, Applicants have not omitted subject matter in the pending claims that is essential.

According to the cited procedural authority, a “claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. [§] 112, first paragraph, as not enabling” (Citation omitted). M.P.E.P. § 2172.01, p. 2100-198, Rev. 1 (Feb. 2003). This procedural authority is referred to below as the “omission provision”.

The Office Action provides no indication of the existence any description to the effect that details concerning the step of predicting resistance are “essential to the invention”. If anything, and as noted hereinabove, the Application tends to indicate precisely the opposite, this is that the claimed subject matter is of general applicability. Therefore, this omission provision does not apply to the pending claims, and the Office Action provides no indication of any description of subject matter as being essential to the invention.

Applicants respectfully submit that the claims do not fail to “interrelate essential elements of the invention as defined ... in the specification”. M.P.E.P. § 2172.01, p. 2100-198, Rev. 1 (Feb. 2003). Applicants note that the present Application provides ample description, illustrations and references to teach, direct and show how such step is performed in a wide variety of general and specific situations, and without relying on a particular limitation.

Details concerning the step of predicting resistance are computing details that are provided and illustrated in the specification. These details are not essential for the claimed methods.

The specification describes how fold resistance is computed and how the prediction of resistance is categorized in terms of the computed fold resistance. Therefore, the step of predicting resistance is not one of arbitrary and undefined performance, but one for which the specification provides teachings and actual computational details. These teachings and computational details, however, are not essential features of the claimed subject matter, and they are not to be read in the claims as limitations therein. Accordingly, such teachings and computational details are not recited in the claims. A person of ordinary skill in the art would therefore know how to implement such step and also be informed on what is being claimed.

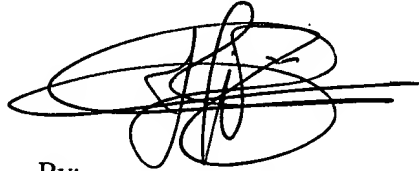
Applicants have addressed the procedural provisions encompassed by the M.P.E.P. section cited in the Office Action, and shown that such provisions do not impede the allowance of the pending claims. Furthermore, for at least the reasons set forth herein,

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Applicants submit that the pending claims comply with 35 U.S.C. § 112 ¶ 2. Applicants respectfully request that the rejections under 35 U.S.C. § 112 ¶ 2 be withdrawn.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "Jesús Juanós i Timoneda", written over a horizontal line.

By: \_\_\_\_\_

Jesús Juanós i Timoneda, PhD  
Reg. No. 43,332

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-1513  
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